

D-2804CON2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In re application of:

BECK et al)	Group Art Unit: N/A
)	(Prior Appln. 1614)
Serial No. N/A)	
)	Examiner: N/A (Prior
)	Appln. Jagoe, D.)
Dated: Filed Herewith)	
)	
For: PRESERVED CYCLODEXTRIN-)	
CONTAINING COMPOSITIONS)	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate these documents as may be appropriate. Applicant requests that these documents be made of record in the above-identified application.

Many of these documents has previously been cited in prior (parent) application Serial No. 09/388,968, filed September 2, 1999. Therefore, no copies of these documents are submitted herewith.

The relevance of the Japanese patents (3048655 and 2-262518) is believed to be as set forth in the Abstracts as follows:

(3048655) - Abstract:

New complex comprises prostaglandin D2 or its lower alkyl ester and beta-cyclodextrin. The complex is prepared by reacting prostaglandin D2 analogue with beta-cyclodextrin in water.

USE/ADVANTAGE - The stable complex can be obtained easily in high yield as well as with high purity, keeping the bioactivity. The new complex is more stable than the ordinary one. Prostaglandin agent can be effectively used

in the treatment of ophthalmic diseases such as glaucoma.

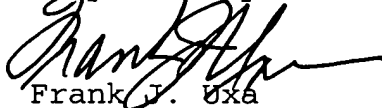
In an example, 12 mg of beta-cyclodextrin was dissolved in water (0.7ml) and 2 mg prostaglandin D2 crystals were added and stirred cooling with ice to obtain plate crystals. The plate crystals were filtered and washed with cold 50% aq.methanol to obtain the clathrate of beta-cyclodextrin and prostaglandin D2 (2:1), which was further dried over P205 in vacuo.

(2262518) ABSTRACT:

An eye lotion for control of intraocular pressure contains as active substance, urapidil (6-((3-(4-o-methoxyphenyl)-1-piperazinyl) propyl) amino) 1,3-dimethyl uracil).

The eye lotion can contain cyclodextrin or its derivs. (e.g. methylated beta-cyclodextrin or hydroxy propyl beta-cyclodextrin). The lotion contains 0.001-40 mg. Esp. 0.5-10 mg of urapidil. Mol ratio of urapidil and cyclodextrin is 1:0.5-3.0. The eye lotion can contain other additives such as pH controllers (e.g. NaOH or acetic acid); isotonic agents (e.g. potassium chloride or sodium chloride); bactericides (e.g. Thimerosal); surfactants (e.g. polyoxy ethylene hardened castor oil); stabilisers (e.g. EDTA); preservers (e.g. methyl p-hydroxy benzoate); or antiseptics (e.g. phenyl ethyl alcohol).

Respectfully submitted,



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Form PTO-1449

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

(Use several sheets if necessary)

DOCKET NO: D-2804 CON2

APPLN. NO.: N/A

APPLICANT: Beck et al

FILING DATE: herewith

GROUP ART: # N/A

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	RULING DATE
	4	3	8	3	9	9	2	05/1983	Lipari			
	5	4	7	2	9	5	4	12/1995	Loftsson			
	0	0	7	6	4	4	9	06/2002	Beck et al.			
	0	1	9	8	1	7	4	12/2002	Lyons			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES	NO
	0	7	9	4	7	8	3	05/2003	Europe				

OTHER DOCUMENTS

		U.S. Patent Application Serial No. 10/764,057, filed January 24, 2004.
		Nina Sadlej-Sosnowska, "Influence of the Structure of Steroid Hormones on Their Association with Cyclodextrins: A High-Performance Liquid Chromatography Study," <i>Journal of Inclusion Phenomena and Molecular Recognition in Chemistry</i> , 27: 31-40, 1997. ✓
		Klein et al., "Predicting the Free Energies of Complexation Between Cyclodextrins and Guest Molecules: Linear versus Nonlinear Models," <i>Pharmaceutical Research</i> , Vol. 17, No. 3, 2000. ✓
		Zhao et al., "Predicting Solubility in Multiple Nonpolar Drugs-Cyclodextrin System," <i>Journal of Pharmaceutical Sciences</i> , Vol. 91, No. 11, November 2002.
		Hirayama et al., "Methods of Investigating and Preparing Inclusion Compounds," Cyclodextrins and Their Industrial Uses, Chapter 4, pp. 113-172, Editor Dominique Duchêne, Editions de Santé, 19, rue Louis-le-Grand, Paris.

EXAMINER

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

(Use several sheets if necessary)

Applicant: **BECK ET AL**Filing Date: **HEREWITH**Group Art Unit: **N/A****U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	RULING DATE IF APPROPRIATE
	4	3	8	3	9	9	2	4/83	LIPARI			
	4	4	7	0	9	6	5	9/84	WOLF ET AL			
	4	7	2	8	5	0	9	3/88	SHIMIZU ET AL			
	4	9	7	5	4	2	8	12/90	SHELL			
	5	0	5	1	4	0	2	9/91	KURIHARA ET AL			
	5	2	2	7	3	7	2	7/93	FOLKMAN			
	5	1	3	4	1	2	7	7/92	STELLA ET AL			
	5	3	3	2	5	8	2	7/94	BABCOCK ET AL			
	5	3	7	6	6	3	2	12/94	KONINGS ET AL			
	5	3	6	2	7	5	8	11/94	AHMED			
	6	1	0	6	7	3	8	8/2000	WOO ET AL			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES	NO
	6	0	5	2	0	3		6/7/94	EP				
	9	4	1	5	5	8	2	21/7/94	PCT				
	3	0	4	8	6	5	5		JAPANESE				
	2	2	6	2	5	1	8		JAPANESE				

OTHER DOCUMENTS

	X	AUSTRALIAN CONVENTION APPLICATION OF PATENT APPLICATION NO. 62-140730.
	X	RAJEWSJI ET AL, JOURNAL OF PHARMA. SCIENCES, VOL. 85, PGS. 1142-1169 NO. 11, 11/96.
	X	LOFTSSON ET AL, DRUG DEVEL. & INDUST. PHARMACY, 18(13), 1477-1484 (1992).
	X	JANSEN ET AL, LENS & EYE TOXICITY RESEARCH, 7(3&4), 459-468 (1990).

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(Use several sheets if necessary)

Docket Number: D-2804 CON 2

Application Number: N/A

Applicant: BECK ET AL

Filing Date: Reswita

Group Art Unit: N/A

EXAMINER
INITIAL

DOCUMENT NUMBER

DATE _____

NAME _____

CLASS

SUBCLASS

RULING DATE
IF APPROPRIATE

DOCUMENT NUMBER

DATE _____

COUNTRY

CLASS

SUBCLASS

TRANSLATION

YES	NO
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NO

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2/98

PCT

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9/84

EP

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PCT

OTHER DOCUMENTS

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